REMARKS

Claims 20, 22-24 and 26-34 were previously pending in the present application. By this amendment, claims 20 and 34 are amended, and new claims 35-43 are added. Accordingly, claims 20, 22-24 and 26-43 are currently pending. No new matter is added by the amendments. Entry of the amendments and reconsideration of the application is respectfully requested in view of the above amendments and the following remarks.

A. Claim Amendments

Claim 20 is amended to delete the limitation of "water soluble." Claim 20 is further amended to specify that the protein, peptide or enzyme is "substantially non-denatured." Basis for the limitation "substantially non-denatured" protein, peptide or enzyme is found at page 6, lines 23-24, and 35 and page 7, lines 5-6.

Claim 34 is amended to depend from claim 20. New claim 35 recites the same limitations as claim 34, but depends from claim 32.

New claims 36 and 37 find basis in the originally filed claim 17.

New claims 38 and 39 specify the limitation "water-soluble" which has been deleted from independent claim 20.

New claim 40 specifies the limitation "substantially non-denatured" protein, peptide or enzyme, the basis for which is found at page 6, lines 23-24, and 35 and page 7, lines 5-6.

New claim 41 specifies most of the limitations of claim 20, except the microparticle size range of 1-10 microns is replaced with "an aerodynamic diameter of less than 5 microns." Support for this limitation can be found in the specification at page 1, line 33, page 35, lines 26-29 and page 36, lines 5-8.

New claim 42 specifies that the microparticles are suitable for delivery to the alveoli, which finds support at page 35, lines 26-29.

New claim 43 specifies "the protein is selected from insulin, parathyroid hormone, alpha-1 antitrypsin and calcitonin," which finds support at page 17, lines 13-15 (insulin, parathyroid hormone, and calcitonin), and alpha-1 antitrypsin at page 17, lines 7-8 and Example 6 (26:23 – 27:14) of the specification.

No new matter is added by the amendments to the claims or newly introduced claims. Entry of the amendments is respectfully requested.

B. Rejections under 35 U.S.C. §102(e)

Claims 20, 22-23 and 26-34 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Platz et al. (U.S. 6,509,006 B1).

While Platz (US Pat. No. 6,509,006) itself is not prior art against the present application, the Examiner argues that the earliest priority document that Platz is entitled to, Ser. No. 07/910,048 (U.S. Pat. No. 5,458,135; "the '135 patent"), discloses relevant material at col. 5, lines 51-67 (device designed to deliver medicaments, drugs and bioactive agents to the lungs as an aerosol) and col. 12, lines 24-27 (spray drying a powder with a solution of mannitol and bovine serum albumin.

(i) Without agreeing with the Examiner's position, but solely to distinguish Platz and expedite prosecution, Applicants have further amended claim 20. Claim 20, as amended, specifies a therapeutic composition comprising dry, discrete microparticles which comprise a water-soluble carrier selected from simple and complex carbohydrates and a therapeutically effective amount of therapeutic agent which is a substantially non-denatured protein, peptide or enzyme. Claim 20 specifies that the carrier and the therapeutic agent are present in the same microparticle, not as separate microparticles.

Column 12, lines 22-32 of the '135 patent states that the test powder is to be spray-dried, it does not teach or suggest that the spray-drying conditions are controlled such that the bovine serum albumin (BSA) does not get denatured. The '135 patent is silent as to the chemical integrity of the BSA protein used in the test powder. The spray-drying parameters for production of the "test powder" are not disclosed in sufficient detail. The spray-drying process disclosed in the '135 patent could well be denaturing for proteins, peptides and enzymes, as no teaching is provided to exclude denaturing conditions. On reviewing the disclosure of the '135 patent, one of skilled in the art would not learn whether the or not the BSA in the test powder is denatured or not.

Since the '135 patent does not teach or suggest a "therapeutic agent [which] is a substantially non-denatured protein, peptide or enzyme," it does not anticipate claim 20, as amended.

(ii) Further, the test powder disclosed in the '135 patent is used to establish whether there is an adequate air supply to disperse the powder. (*see* '135 patent, col. 12, lines 27-29). The only requirement for the test powder in the '135 patent is its ability to be delivered from a device. Claim 20 specifies a "therapeutically effective amount of therapeutic agent." There is no requirement for the protein in the '135 patent to be "therapeutically active" and there also is no requirement for the BSA to remain non-denatured.

The '135 patent teaches that typically only lyophilized proteins or peptides are used in an inhaler. (col. 7, lines 58-60). Notably, the '135 does not disclose a water-soluble carrier with a lyophilized protein or peptide.

(iii) Applicants traverse the Examiner's statement that "the particles contain a drug (i.e., protein)" in response to Applicant's arguments (in the response filed January 29, 2007) that BSA is a carrier. According to Platz (the '006 patent) the "types of pharmaceutical excipients that are useful as carriers include a stabilizer such as human serum albumin (HSA)." (the '006 patent; col. 6, lines 51-53; emphasis added). Example VII in Platz (cols. 15-16) discloses a beta-interferon formulation where the serum albumin (HAS) is used as a carrier.

In light of the teaching of Platz ('006 patent) that serum albumins are used as carriers, the Examiner's contention that bovine serum albumin in the '135 is a "drug" to satisfy the limitation of a "therapeutically effective amount of therapeutic agent" cannot be justified.

Applicants further note that even the present application discloses BSA as a "carrier" and not as a therapeutic agent. (Specification, page 5, line 28 to page 6, line 1; page 17, lines 25-26). Claim 20 specifies a therapeutic agent in addition to a carrier.

In view of Platz ('006 patent) and the present application, BSA can only be characterized as a carrier and not as a therapeutic agent. Therefore, there is no therapeutic agent specified in the test powder of the '135 patent, when reviewed in light of the Platz ('006) disclosure.

Since there is no disclosure of microparticles comprising a "therapeutically effective amount" of a "substantially non-denatured" therapeutic agent in combination with a water-soluble carrier in the '135 patent, Platz does not teach each and every limitation of claim 20, as amended. Claims 22-24 and 26-31 depend from claim 20.[1] Therefore, Applicants respectfully request withdrawal of the rejection of claims 20, 22-24 and 26-31 under 35 U.S.C. §102(e).

(iv) Independent claim 32 stands rejected as anticipated on the same grounds as claim 20 as being anticipated by Platz ('006 patent) in view of the disclosure of its parent Patton ('135) patent. Applicants respectfully traverse.

The present application is a continuation of U.S. App. Ser. No. 08/487,420 (issued as US Pat. No. 5,993,805) filed June 7, 1995. For Platz to anticipate claim 32, it must rely on the teaching of the '135 patent.

Claim 32 specifies "wherein the therapeutic agent is a protein selected from the group consisting of insulin, parathyroid hormone, alpha-1 antitrypsin and calcitonin." There is no teaching or suggestion in the '135 patent of "insulin, parathyroid hormone, alpha-1 antitrypsin and

[1] Applicants note that microparticles in the form of free-flowing powder as specified in claim 29, is not disclosed in the '135 patent.

calcitonin." The mere teaching of a protein in the '135 patent cannot anticipate the specific limitations of "insulin, parathyroid hormone, alpha-1 antitrypsin and calcitonin."

Therefore, Applicants respectfully request withdrawal of the rejection of claim 32 and claims 33-40 which depend therefrom as being anticipated by Platz.

(v) New claim 41 specifies "said microparticles have an aerodynamic diameter of less than 5 microns." The '135 patent does not teach or suggest microparticles with an aerodynamic diameter of less than 5 microns, especially at column 12, lines 24-27 where the allegedly anticipating disclosure is found according to the Examiner's contention.

Therefore, Platz in view of the '135 patent disclosure does not anticipate new claim 41 and claims 42-43 with depend therefrom.

In light of the arguments presented above, Applicants respectfully request withdrawal of the rejection of the claims under 35 U.S.C. § 102(e) by Platz et al. (U.S. 6,509,006 B1).

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to allow this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to ***Deposit Account No. 03-1952*** referencing docket no. 263742002802. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By _____
Shantanu Basu
Registration No.: 43,318

MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-5995